

Complete Summary

GUIDELINE TITLE

Tissue sampling and analysis.

BIBLIOGRAPHIC SOURCE(S)

Faigel DO, Eisen GM, Baron TH, Dominitz JA, Goldstein JL, Hirota WK, Jacobson BC, Johanson JF, Leighton JA, Mallery JS, Peterson KA, Raddawi HM, Varg JJ 2nd, Waring JP, Fanelli RD, Wheeler-Harbough J. Tissue sampling and analysis. *Gastrointest Endosc* 2003 Jun;57(7):811-6. [91 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Malignant, inflammatory, and infectious processes of the esophagus, stomach, small intestine, and colon that require tissue sampling and analysis

GUIDELINE CATEGORY

Diagnosis
 Evaluation

CLINICAL SPECIALTY

Gastroenterology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide a practical basis for tissue analysis (biopsy, snare excision, cytology, and culture) during gastrointestinal (GI) endoscopy

TARGET POPULATION

Patients with suspected or confirmed gastrointestinal malignancy, inflammation, or infection

INTERVENTIONS AND PRACTICES CONSIDERED

1. Tissue sampling techniques
 - Pinch forceps biopsy
 - Brush cytology
 - Snare excision
 - Fine-needle aspiration (FNA)
2. Endoscopy
3. High-resolution magnifying endoscopy
4. Chromoendoscopy
5. Flexible sigmoidoscopy
6. Colonoscopy
7. Systematic biopsy
8. Four-quadrant biopsy
9. Endoscopic mucosal resection (EMR)
10. Brushing culture
11. Viral culture
12. Helicobacter pylori testing
 - Gastric biopsy
 - Rapid urease test (RUT)
13. Gastric polypectomy
14. Colon polypectomy

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consensus.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guidelines for the appropriate use of endoscopy are based on a critical review of the available data and expert consensus.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations are followed by evidence grades (A-C) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

Histopathologic evaluation is helpful to differentiate malignant, inflammatory, and infectious processes. Tissue biopsy specimens are routinely obtained from any suspicious lesion during endoscopic evaluation. When the gross endoscopic appearance is normal, histologic analysis may still provide useful information. Tissue analysis is occasionally performed to document the outcome of prior endoscopic or medical therapy. When the gross endoscopic appearance reveals a specific condition, tissue analysis is unnecessary if therapy will not be altered. Tissue biopsy should be avoided when there is an increased potential for hemorrhage such as in patients with coagulopathies.

Techniques

Numerous techniques and devices have been designed to obtain adequate tissue samples. Pinch biopsy is done with biopsy forceps and is the most commonly used form of tissue sampling. Multiple biopsies improve the diagnostic yield; the size, location, specimen orientation, fixation, and staining are also important. Pinch biopsy forceps usually obtain mucosal specimens. Occasionally, jumbo biopsy forceps may also reach the submucosa. However, these forceps require a biopsy channel of at least 3.6 mm and yield 2 to 3 times the surface area but are not generally deeper specimens. Brush cytology may be a useful adjunct to pinch biopsy and helpful in the diagnosis of certain malignancies and infections. Snare excision is used for removal of large polyps. A combination of techniques can increase diagnostic accuracy. Endoscopic ultrasound (EUS)-guided fine-needle aspiration (FNA) is capable of sampling subepithelial lesions and those extrinsic to the gastrointestinal (GI) tract such as lymph nodes and pancreatic masses and is more fully discussed in the American Society for Gastrointestinal Endoscopy (ASGE) Status Evaluation Report "Tissue Sampling During Endosonography."

Esophagus

Malignant tumors of the esophagus can be diagnosed by biopsy alone in 95% of cases, except when obstruction prevents adequate visualization and biopsy of the lesion. Eight to 10 biopsy specimens should be obtained. The addition of brush cytology may increase the diagnostic yield. The most common inflammatory condition, reflux esophagitis, occurs in patients with gastroesophageal reflux disease (GERD). Endoscopy with tissue analysis is indicated to evaluate for the presence of Barrett's esophagus or to rule out infection or malignancy masquerading as gastroesophageal reflux disease. Erosive changes seen on endoscopy correlate well with histology, but isolated erythema is an unreliable criterion for esophagitis. Conversely, abnormal histology (inflammatory cell infiltration with polymorphonuclear cells or eosinophils) may be found by biopsy in

patients with reflux symptoms who have normal-appearing esophageal mucosa. Biopsy and cytology specimens of abnormal-appearing mucosa may be needed to exclude malignancy, infectious esophagitis, certain autoimmune disorders, and to detect Barrett's esophagus.

Barrett's esophagus is a condition in which the normal squamous mucosa is replaced by metaplastic specialized intestinal epithelium and requires endoscopic biopsy for diagnosis. Patients with Barrett's esophagus are at increased risk for esophageal adenocarcinoma, and their identification allows for inclusion in surveillance programs. Histopathology reveals columnar epithelium without a brush border and is distinguished from gastric mucosa by the identification of goblet cells, which may be aided by the use of special stains (alcian blue). Severe ulcerative esophagitis may obscure underlying Barrett's mucosa, and inflammation-induced atypia may be confused with dysplasia. In these instances, aggressive medical therapy to heal esophagitis clarifies subsequent histopathologic interpretation.

Biopsies are also performed to detect dysplasia or adenocarcinoma. If dysplasia is known or suspected to be present, then 4-quadrant biopsies at 1- to 2-cm intervals with additional specimens from any mucosal abnormalities should be taken. A 2-cm protocol missed 50% of cancers in patients with high-grade dysplasia, which were detected in a 1-cm protocol. Although large-capacity "jumbo" forceps have been advocated, a retrospective study found that 4-quadrant biopsies every 2 cm missed the same proportion of cancers when done with large-capacity (4/12, 33%) or standard-sized (6/16, 38%) forceps. The turn-and-suction technique is advocated, in which the open forceps is drawn close to the endoscope's tip, the scope turned toward the wall, suction applied, the forceps advanced, closed, and the specimen obtained. For patients with high-grade dysplasia who opt against esophagectomy, this technique performed at 3- to 6-month intervals has been reported to accurately detect carcinoma, 96% of which were confined to the mucosa.

High-resolution magnifying endoscopy and chromoendoscopy with methylene blue has been advocated to increase the detection of short-segment Barrett's esophagus by directing biopsy location. Chromoendoscopy with Lugol's solution and methylene blue has been reported to increase the detection of squamous cell carcinoma and neoplastic areas within Barrett's esophagus, respectively, although the value of methylene blue in the surveillance of Barrett's esophagus has been questioned. Analyzing the biopsy specimens with flow cytometry and DNA analysis may identify patients with aneuploidy, polyploidy or 17p (p53) loss-of-heterozygosity and predict an increased cancer risk.

Discrete lesions of the esophagus may be removed by endoscopic mucosal resection (EMR). This involves a submucosal injection of saline to raise the lesion followed by snare-cautery excision. This technique has been successfully used on neoplastic lesions arising in Barrett's esophagus and for benign esophageal tumors.

Infectious esophagitis occurs primarily in immunocompromised patients such as those on systemic anti-immune therapy, inhaled steroids, patients with cancer (especially those on chemotherapy), those with diabetes, and patients with acquired immunodeficiency syndrome (AIDS). The most common infectious

agents are *Candida* species, Herpes simplex virus (HSV), and cytomegalovirus (CMV). Fungal esophagitis appears endoscopically as white plaques over the inflamed mucosa. Brushings and biopsy specimens are obtained, but brush cytology is more sensitive. Viral esophagitis manifests as ulcers. Specimens should be taken from both the edge and the center of the ulcer. Histopathology is usually diagnostic but multiple specimens (up to 10) may be required in patients with AIDS. Viral culture may help provide a definitive diagnosis but may be less sensitive than histology for CMV.

Stomach

Gastric neoplasia can present as an ulcerative, polypoid, or submucosal lesion, or as thick gastric folds. Adequate tissue sampling sometimes requires a combination of techniques. Pinch biopsy has the highest diagnostic yield for ulcerative or polypoid masses. Multiple biopsy specimens should be obtained from the edge of each quadrant of an ulcer and from the base. Brush cytology may increase the yield over biopsy alone. Biopsy should be performed on polypoid lesions, and polyps greater than 2 cm should be removed when technically feasible. Gastric polypectomy may carry a higher risk of bleeding than colon polypectomy; therefore, post-procedure acid suppressive therapy should be considered.

EMR is used in the stomach to sample thick gastric folds to exclude malignancy, and for treatment of early gastric cancer (EGC). Candidate early gastric cancer lesions for EMR are generally less than 20 mm and confined to the mucosa by endoscopic ultrasound or endoscopic criteria. The lesion is lifted from the submucosa by an endoscopic fluid injection, and the lesion excised by using one of several described techniques (see Technology Status Evaluation Report - Endoscopic Mucosal Resection).

Patients with peptic ulcer disease, gastric mucosa-associated lymphoid tissue (MALT), lymphoma, and possibly those at increased risk for developing gastric cancer (e.g., family or personal prior history of gastric cancer) should all have their *Helicobacter pylori* status determined. Tissue-based tests are performed on endoscopically obtained forceps biopsies of gastric mucosa. These include testing the sample for urease activity (rapid urease test), histologic examination for typical curved bacilli, and culture. In untreated patients, biopsy specimens should be obtained from the lesser curvature of the antrum near the incisura angularis. Rapid urease tests (RUT) are inexpensive, highly specific, and can be performed in the endoscopy unit providing results in 1 hour. Less-than-perfect sensitivity has led to recommendations that a second test be performed if the rapid urease test is negative. Specimens submitted for histologic examination should be assessed for the presence of inflammatory cells and for typical curved bacilli, the latter of which may require the use of special stains. The presence of significant gastric inflammatory cell infiltration in the absence of bacteria should prompt additional testing with serology, a urea-breath test, or stool antigen testing. Bacterial culture allows for determination of antimicrobial resistance but lacks sensitivity and is cumbersome to perform. The sensitivity of these tissue-based tests may be decreased in patients using proton pump inhibitors or antibiotics, those who have recently been treated for *H. pylori* (but may have persistent infection), or in the setting of gastrointestinal bleeding. In these patients, multiple biopsy specimens from the antrum and corpus should be obtained, and a negative rapid urease test should be confirmed with an alternative test. If possible, patients should be asked

to cease taking proton pump inhibitors for at least 1 week before testing for H pylori.

Small Intestine

Biopsy is an essential part of the investigation of patients with suspected small bowel disease. Peroral biopsy samples have traditionally been obtained from the region of the ligament of Treitz. Endoscopic biopsy is now more commonly used and has the advantage of being a shorter, more comfortable procedure wherein multiple directed biopsy specimens can be obtained. Pinch biopsies will usually yield tissue adequate for diagnosis in diffuse mucosal disease if at least 3 biopsy specimens are taken from a site distal to the duodenal bulb in order to avoid misinterpretation of biopsy findings related to Brunner's glands. In diseases in which involvement may be patchy, multiple biopsies from more distal sites of the small intestine using longer and smaller-caliber endoscopes may be necessary. Biopsy may be useful in establishing the diagnosis even in macroscopically normal tissue.

Small bowel biopsies remain the reference standard for accurately diagnosing mucosal malabsorption syndromes. A small bowel biopsy is still considered necessary to confirm the suspicion of celiac disease, even in the presence of positive screening blood tests (e.g., endomysial antibodies or tissue transglutaminase). This should be done before treatment is started, because false-positive blood tests may occur.

Infection of the small bowel may be diagnosed by histologic examination. *Giardia lamblia* and a number of other protozoal agents may be associated with inflammatory changes in the small intestinal mucosa, and detection of the mature adult organism, its trophozoites, or a component of the life cycle in or on the surface epithelium may lead to a specific diagnosis. In some patients the morphologic appearance may be similar to eosinophilic gastroenteritis, a diagnosis that can only be established after parasitic disease has been excluded.

Patients with immunodeficiency, including post-transplantation or human immunodeficiency virus (HIV) infection, may harbor agents such as *Isospora belli*, *Cryptosporidia*, *Cyclospora*, and *Microsporidia*, which may be detected on small intestinal biopsy specimens. Other pathogens detected on a small bowel biopsy in an immune deficient patient include CMV, fungal organisms such as *Candida* species and histoplasmosis, and *Mycobacterium avium-intracellulare* complex. It may be useful to use a large cup jumbo forceps rather than a conventional biopsy forceps if two biopsy specimens are to be taken in sequence before withdrawing the biopsy forceps (Double-bite technique). It is also advisable to use a needle to transfer the biopsy out of the forceps to the fixative rather than shaking it off in a fixative bottle because this may alter the surface epithelium and result in the loss of any adherent exudates.

Tumors of the duodenum should be evaluated by endoscopy and biopsy. The choice of forward- or side-viewing instruments and sampling technique depends on the location and size of the tumor.

Duodenal, jejunal, and gastric polyps may occur in 33 to 100% of patients with familial adenomatous polyposis (FAP). Gastric polyps in patients with FAP are

most often fundic gland polyps, which have no malignant potential, but biopsy should be considered to exclude adenoma. Duodenal polyps are typically adenomatous and occur primarily in the ampulla or periampullary region. Upper gastrointestinal polyps may appear synchronous or metachronous to the identification of colonic polyps. Adenocarcinoma developing from periampullary adenomas is a well-recognized entity and is the most common cause of death in patients with FAP once colorectal cancer is excluded. Although its efficacy is yet to be established, a surveillance program is advisable. There are case reports of pancreatitis related to endoscopic biopsy of the papilla. Despite this, complications related to endoscopic biopsy or removal of duodenal adenomas at a distance from the papilla appears to be uncommon.

Colon

Previous guidelines have outlined the general indications for colonoscopy and biopsy in patients with colonic polyps and inflammatory bowel disease.

Visual evidence of a lesion warrants histopathologic evaluation. If lesions are too numerous for removal, representative samples should be obtained for analysis. Diminutive polyps found during screening sigmoidoscopy should be biopsied; larger polyps should be completely removed at subsequent colonoscopy. Detection of adenomas or carcinoma is an indication for complete examination of the colon. The published reports as to the significance of hyperplastic polyps detected during sigmoidoscopy remains conflicted, although most gastroenterologists in the United States do not feel that these polyps indicate an increased risk of harboring significant proximal neoplasia.

For the evaluation of colitis, endoscopy and biopsy may be useful in distinguishing between different causes of colitis, assisting in the management of inflammatory bowel disease, and establishing the extent of bowel involved. Biopsy specimens obtained during the acute phase of a bloody diarrheal illness may differentiate acute self-limited colitis from an initial or recurrent attack of chronic ulcerative colitis or ischemic colitis. Terminal ileal biopsy may be useful in the diagnosis of Crohn's disease, infectious ileitis, and lymphoid nodular hyperplasia. Both Crohn's disease and ulcerative colitis are associated with an increased risk of developing colorectal cancer. Surveillance colonoscopy looking for dysplasia is recommended, beginning at 8 years of disease when the cancer risk starts to increase. A longer delay is suggested in patients with left-sided disease only (e.g., 15 years). In patients with pancolitis, 4-quadrant biopsy specimens taken every 10 cm, with biopsies every 5 cm in lower 25 cm, is a frequent approach. In cases of left-sided colitis, specimens should also be taken in the proximal colon to reassess extent of disease.

The approach to dysplastic lesions in patients with chronic colitis is evolving. When dysplastic mass lesions are large, irregular, or associated with strictures, surgery is required. However, when typical-appearing adenomas are encountered in a colitic segment they should be removed and the surrounding mucosa biopsied. If the polyp is completely removed and there is no surrounding dysplasia, then this may be regarded as an adequately treated sporadic adenoma and endoscopic surveillance continued.

It remains unclear as to the number and location that biopsy specimens should be taken in assessing a patient with chronic diarrhea and a grossly normal colon. Microscopic colitis is diagnosed by compatible histologic features in a patient with chronic watery diarrhea whose endoscopic and microbial evaluations are normal. Biopsy specimens taken during a flexible sigmoidoscopy may be adequate to diagnose this disease entity.

Summary

Tissue sampling is useful in differentiating malignant, inflammatory, and infectious processes [C]. Techniques include pinch forceps biopsy, brush cytology, snare excision, and fine-needle aspiration [B]. For malignant lesions, maximal yield is attained with 8 to 10 biopsies [A]. Patients with Barrett's esophagus should undergo systematic biopsy to evaluate for dysplasia [C]. Patients with Barrett's esophagus and high-grade dysplasia should have 4-quadrant biopsies performed every 1 to 2 cm to detect underlying carcinoma [A, B]. Endoscopic mucosal resection may be used to remove malignant or premalignant mucosal lesions [B]. Infectious conditions require multiple biopsies, and if ulcers are present these should be obtained from both the center and edge; brushing and viral culture are adjunctive techniques [B]. H pylori infection can be assessed by gastric biopsy submitted for histologic examination or rapid urease test [A]. Biopsy of the incisura angularis gives the highest yield for H pylori in untreated patients, but those who have been treated or are taking proton pump inhibitors or antibiotics should have specimens of the corpus and fundus taken as well [A]. Gastric polyps should be extensively sampled or removed when feasible [C]. Gastric polypectomy may carry a higher risk of bleeding than colon polypectomy and postprocedure acid suppressive therapy should be considered [B]. Random biopsies of the small intestine are indicated in the evaluation of diarrheal states, celiac disease, or infections [C]. Duodenal adenomas may be sporadic or associated with FAP and should be sampled or removed when feasible [C]. Colon lesions should be endoscopically excised (polypectomy, EMR) or sampled if lesions are too numerous or removal is not technically feasible [C]. In patients with acute colitis, biopsy may help establish an etiology [B]. Patients with longstanding chronic colitis should undergo systematic surveillance to detect dysplasia, which may indicate an increased risk of cancer [B]. In patients with diarrhea, random biopsy of normal-appearing colonic mucosa may reveal microscopic colitis [B].

Definitions

- A. Prospective controlled trials
- B. Observational studies
- C. Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and classified for some of the recommendations using the following scheme:

- A. Prospective controlled trials
- B. Observational studies
- C. Expert opinion

When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate utilization of tissue analysis (biopsy, snare excision, cytology, and culture) during gastrointestinal endoscopy

POTENTIAL HARMS

There are case reports of pancreatitis related to endoscopic biopsy of the papilla. Despite this, complications related to endoscopic biopsy or removal of duodenal adenomas at a distance from the papilla appears to be uncommon.

CONTRAINDICATIONS

CONTRAINDICATIONS

Tissue biopsy should be avoided when there is an increased potential for hemorrhage such as in patients with coagulopathies.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Faigel DO, Eisen GM, Baron TH, Dominitz JA, Goldstein JL, Hirota WK, Jacobson BC, Johanson JF, Leighton JA, Mallery JS, Peterson KA, Raddawi HM, Varg JJ 2nd, Waring JP, Fanelli RD, Wheeler-Harbough J. Tissue sampling and analysis. *Gastrointest Endosc* 2003 Jun;57(7):811-6. [91 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jun

GUIDELINE DEVELOPER(S)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society for Gastrointestinal Endoscopy

GUIDELINE COMMITTEE

Standards of Practice Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American Society for Gastrointestinal Endoscopy \(ASGE\) Web site](#).

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 23, 2005. The information was verified by the guideline developer on March 31, 2005.

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